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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,901	09/19/2001	Norman J. Dovichi	45504-019	2915
20277	7590	02/18/2004	EXAMINER	
MCDERMOTT WILL & EMERY 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			LUDLOW, JAN M	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,901

Applicant(s)

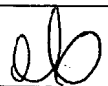
DOVICH, NORMAN J.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 31, 2003, requesting entry of the amendment filed October 16, 2003, has been entered.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

3. A person shall be entitled to a patent unless –

4. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

8. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

10. Determining the scope and contents of the prior art.
11. Ascertaining the differences between the prior art and the claims at issue.
12. Resolving the level of ordinary skill in the pertinent art.
13. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-4, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/33989 (WO).

16. WO teaches a first electrophoresis capillary 56, a second electrophoresis capillary 116 and interface 80 with reagent inlet 84 and waste outlet 76. Detectors 52 and 88 are provided and power supplies 60 and 92 are used to perform the electrophoresis. Detectors include fluorescence detectors (p. 13, line 4) and the types of electrophoresis include isoelectric focusing and sieving (p. 17, lines 20-25). Added reagents include enzymes and antibodies (p. 20, lines 13-21), which constitute derivatizing agents in that they react with the analytes to form derivative products, such as degradation products and bound complexes. In addition, components can be fluorescently labeled (p. 13-15). WO further teaches a method of introducing fractions from the first channel to the second channel by transferring aliquots at predetermined regular time intervals. Subsequent aliquots are transferred after the preceding aliquot has traveled far enough into the second channel (p. 20, first paragraph). See also the

example on page 21 in which a mixture of carbohydrates is separated in a first electrophoresis capillary, a first selected component is transferred to the second electrophoresis capillary with selected enzyme reagents and the reaction products separated in the second capillary, and the process repeated so as separate the mixture in the first capillary and perform sequencing in the second.

17. WO fails to explicitly teach separately passing the fractions through the second channel. (Note that "receive separately" and variations thereof have been interpreted in view of the specification (p. 22, lines 15-22) to mean that only one fraction is separated in the second dimension at one time.)

18. It would have been obvious to wait until a preceding sample exited the second channel before injecting a subsequent sample if one were willing to forego the timesavings of injecting the second sample when the preceding sample was sufficiently far along in the channel not to interfere with the subsequent sample. Alternatively, it would have been obvious to practice the sequential method of page 21 by injecting the enzymes (derivatizing agent) in the interface in order to use the reagent inlet for its known purpose. It would have been obvious to perform sieving electrophoresis as the second form of capillary electrophoresis in order to classify separated components by molecule weight using a technique taught by WO.

19. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO as applied to claims above, and further in view of Moring.

20. WO fails to teach adding fluorescent label at the interface.

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21. Moring teaches an interface similar to that of WO. Fluorescent label may be added at the interface (see, e.g., abstract).

22. It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the label at the interface in WO in order to add the label at an alternative point in the reaction and separation sequence as taught by Moring.

23. Claims 5-9, 16-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO as applied to claims above, and further in view of Yeung et al.

24. WO fails to teach a plurality of interfaces in a manifold.

25. Yeung et al teaches a system for performing chromatography followed by electrophoresis or other separation. A manifold 26 connects channel 90 to valve 22, which is connected to a syringe pump 19, and a variety of reservoirs via ports 53-57 (col. 11, lines 41-59). The manifold is also coupled to interfaces 32 which couple the chromatographic columns 14 to the electrophoresis capillaries 33 and outlet channels coupled to manifold 31. Laser induced fluorescence is used to detect separated components (e.g., col. 21, line 17).

26. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a manifold as taught by Yeung in the apparatus and method of WO in order to perform plural simultaneous separations with reagent addition at the interface as taught by Yeung. It would have further been obvious to use laser induced fluorescence as the fluorescence detection in WO in order to provide an art recognized alternative detection system as taught by Yeung. With respect to claim 9, it would have been obvious to use a known electrophoresis fluorescence detector for its known

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purpose. Note that applicant admits that the sheath flow detector with camera, filter and prism is known in the prior art, e.g., from Patent No. 5567294 issued October 22, 1996 (see page 25 of the instant disclosure). With respect to claims 19-20, it would have been obvious to use a known sample application device for separating components of a single cell. Note that applicant admits on pages 12-13 that the sample application device is known from documents published in 1995-1997.

27. Claims 1, 4-5, 7-9, 10, 13-14, 17-20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeung in view of WO 95/33989 (WO).

28. Yeung et al teaches a system and method for performing chromatography followed by electrophoresis or other separation. A manifold 26 connects channel 90 to valve 22, which is connected to a syringe pump 19 and a variety of reservoirs via ports 53-57 (col. 11, lines 41-59). The manifold is also coupled to interfaces 32 which couple the chromatographic columns 14 to the electrophoresis capillaries 33 and outlet channels coupled to manifold 31. Laser induced fluorescence is used to detect separated components (e.g., col. 21, line 17).

29. Yeung fails to teach sequential injection of fractions.

30. The teachings of WO are given above.

31. It would have been obvious inject sequential fractions from the first separation channel into the second channel in order to provide an alternative injection scheme as taught by WO. It would have been obvious to wait until a preceding sample exited the second channel before injecting a subsequent sample if one were willing to forego the time savings of injecting the second sample when the preceding sample was sufficiently

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far along in the channel not to interfere with the subsequent sample. With respect to claim 9, it would have been obvious to use a known electrophoresis fluorescence detector for its known purpose. Note that applicant admits that the sheath flow detector with camera, filter and prism is known in the prior art, e.g., from Patent No. 5567294 issued October 22, 1996 (see page 25 of the instant disclosure). With respect to claims 19-20, it would have been obvious to use a known sample application device for separating components of a single cell. Note that applicant admits on pages 12-13 that the sample application device is known from documents published in 1995-1997.

32. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yeung and WO as applied to claims above, and further in view of Moring.

33. Yeung fails to teach adding fluorescent label at the interface.

34. Moring teaches an interface similar to that of Yeung. Fluorescent label may be added at the interface (see, e.g., abstract).

35. It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the label at the interface in Yeung in order to add the label at an alternative point in the reaction and separation sequence as taught by Moring.

36. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Khan et al is related to WO 95/33989.

37. Applicant's arguments filed October 16, 2003 and reiterated December 31, 2003 in filing the RCE have been fully considered but they are not persuasive.

38. Applicant argues that the time-based aliquot embodiment of WO does not teach a fraction in the sense of the instant invention, but points to no language requiring that a

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fraction is a single band and nothing more. In fact, applicant points out that on page 10, lines 23-25 of the instant specification, a fraction "may contain one or more components" and therefore if an aliquot contains more than one component, it still constitutes a fraction as defined in the instant disclosure. The aliquots of WO are fractions based on timed collection, and since they have passed through the first separation means, they are the results of a separation process, contrary to applicant's opinion. The examiner notes that on page 20, line 4 of the instant application, applicant uses the term "aliquot" as an alternative to "fraction". The examiner also notes that WO teaches a detector 52 for detecting bands exiting the first capillary and basing the transfer of the bands to the second capillary on detection by detector 52 (p. 18).

39. Further, the instant claims do not preclude passage of aliquots containing no components (other than the carrier fluid) between aliquots containing components (other than the carrier fluid), and the claims further do not preclude the carrier as a component. Further still, the instant apparatus claims do not include a controller operative to perform the method (nor is a controller disclosed), and the prior art device is capable of the intended use stated in the apparatus claims.

40. Applicant argues that the selected component-based aliquot embodiment of WO does not teach a fraction in the sense of the instant invention in that the instant fraction contains one or more components of interest, but points to no portion of WO requiring that the component is pure prior to the second separation, and fails to understand that even if the component of WO is pure, it constitutes a fraction as defined herein by

containing "**one**" in the "**one** or more components" constituting a fraction as defined in the instant application.

41. The examiner notes that a typographical error exists in the previous office action, and claims 1-4, 10-14 should have been rejected under 35 USC 103(a) over WO. In that all the features of claims 13 and 14 are addressed in the rejection, it is clear that the claims were rejected.

42. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

43. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-

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1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
February 9, 2004